

REMARKS

The Office Action dated February 24, 2005 has been carefully considered. Applicants understand that the Examiner does not agree with regard to Applicants' traverse over the restriction requirement and that claim 3, 6, 8, 9 and 11 have been withdrawn from further consideration. Upon the allowance of a generic claim, Applicants reserve the right to request reconsideration on this issue.

The declaration in this application has been objected to as defective by reason that, in the Examiner's view, it does not identify the city and state of the residence of the inventors. Applicants' present attorney believes that the Examiner has overlooked the application data sheet filed by Applicants' prior attorneys. For the convenience of the Examiner, the transmittal letter and the application data sheet referred to in the transmittal are attached hereto as Exhibit A. In light of this application data sheet which sets forth the addresses of the inventors, Applicants believe that this objection should be withdrawn.

The specification has been objected to on the ground that it incorporates "essential material...by reference to a foreign application or patent, or to a publication..." Applicants find no incorporation by reference of any such material in the present application. If the Examiner is referring to the publication identified at page 3, lines 1-3, of the present application, it is pointed out that this is simply a reference to "relevant literature" and is not incorporated by reference in the present application. Thus, it is believed that this objection should be withdrawn.

The Examiner has objected to the Information Disclosure Statement filed on October 26, 2004 with regard to the Hudgins Thesis and asks for a citation of relevant pages. Since this document is being cited in an IDS and it consists only of a single document, not a compendium of different publications or theses, the answer to the Examiner's question is all of the pages, i.e., pages 1-209. The Examiner's reference to 37 CFR 1.98(b)(5) is misplaced because that rule applies only to publications such as books

or magazines which contain chapters or articles by different authors on different subjects. The Hudgins Thesis is a single document having a single author. Thus, it is respectfully requested that this objection be withdrawn.

Claims 1-2, 10, 12-16, 23 and 47-48 have been rejected as anticipated by Stubstad Patent No. 3,867,728. The claims have been amended in a manner which is believed to more fully bring out the patentable distinction between the present invention and the Stubstad patent. In this regard, all of the claims under consideration have been amended to recite that the endplates comprise an interface element adapted to interface with a vertebral body fixation element. This interface element is illustrated as element 57 in Figure 5A.

The Stubstad patent does not disclose endplates of the type recited in the presently-presented claims. Rather, Stubstad describes a top element 11 and a bottom element 12 which are covered with fabric as described at column 8, lines 2-8, which fabric is provided for the purpose of inviting tissue ingrowth. In other words, the replacement disc of Stubstad is not directly attached to the vertebrae above and below the space in which the replacement disc is deployed, but rather that disc is deployed with the hope that tissue ingrowth will fix it in the proper location. Applicants believe this to be an unreliable manner of installing a replacement disc. In contrast, as disclosed in the present application in paragraph 0064-0065 and illustrated in figures 8-11, the vertebral body fixation element 71a and 71b are first firmly attached to their respective vertebrae by driving spikes 55 into the vertebrae and the prosthetic disc with its attached endplates is then installed by interfacing the endplates with the vertebral body fixation elements. Thus, the Stubstad patent, which discloses no such arrangement nor anything similar to it, does not anticipate the claims as amended. Furthermore, there is no suggestion in Stubstad of providing endplates of the type recited in the claims as amended.

In the interest of advancing prosecution, Applicants note that Baumgartner Patent No. 5,370,697, which was cited in Applicants' IDS filed on October 26, 2004 discloses upper and lower supports 2 and

3, but Applicants submit that these supports are not vertebral body fixation elements because they are not attached to a vertebral body by affirmative means. Rather, at column 3, lines 53-59 describe combining the upper and lower supports with a wire mesh to promote tissue ingrowth. Thus, as in Stubstad, the replacement disc is not directly attached to the vertebral body. In addition, there is no suggestion in Stubstad or Baumgartner for combining the teachings of those patents.

Accordingly, Applicants believe that each of the claims, as amended, cannot be considered to be anticipated by Stubstad and patentably distinguish from that reference. A favorable action is respectfully solicited.

The Commissioner is authorized to charge \$225.00 for the two-month extension fee to Orrick Herrington & Sutcliffe LLP's Deposit Account No. 150665 and any fee which may be required in connection with this Amendment to deposit account No. 150665.

Dated: July 15, 2005

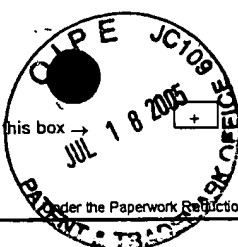
Respectfully submitted,

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**UTILITY
PATENT APPLICATION
TRANSMITTAL**

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.

DKIM-001

First Inventor

Daniel H. Kim

Title

PROSTHETIC INTERVERTEBRAL DISC AND METHODS FOR
USING THE SAME

Express Mail Label No.

EV334001051US

APPLICATION ELEMENTS

SEE MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO:

Commissioner for Patents
Mail Stop Patent Application
P.O. Box 1450
Alexandria, VA 22313-1450

1. ☐ Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)
2. ☒ Applicant claims small entity status.
See 37 CFR 1.27.
3. ☒ Specification [Total Pages: 25]
(preferred arrangement set forth below)
-Descriptive title of the invention
-Cross Reference to Related Applications
-Statement Regarding Fed sponsored R & D
-Reference to sequence listing, a table,
or a computer program listing appendix
-Background of the Invention
-Brief Summary of the Invention
-Brief Description of the Drawings (if filed)
-Detailed Description
-Claim(s)
-Abstract of the Disclosure
4. ☒ Drawing(s) (35 U.S.C. 113) [Total Pages: 11]
5. Oath or Declaration [Total Pages: 1]
a. ☒ Newly executed (original or copy)
b. ☐ Copy from a prior application (37 CFR 1.63 (d))
(for continuation/divisional with Box 18 completed)
i. ☐ **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s)
Named in the prior application, see 37 CFR
1.63(d)(2) and 1.33(b)
6. ☒ Application Data Sheet. See 37 CFR 1.76

7. ☐ CD-ROM or CD-R in duplicate, large table or
Computer Program (Appendix)
8. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
a. ☐ Computer Readable Form (CRF)
b. Specification Sequence Listing on:
i. ☐ CD-ROM or CD-R (2 copies); or
ii. ☐ paper
c. ☐ Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & documents(s))
10. ☐ 37 CFR 3.73(b) Statement ☐ Power of Attorney
(when there is an assignee)
11. ☐ English Translation Document (if applicable)
12. ☐ Information Disclosure ☐ Copies of IDS Citations
Statement (IDS)/PTO-1449
13. ☐ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
16. ☐ Nonpublication Request under 35 U.S.C. 122
(b)(2)(B)(i). Applicant must attach form PTO/SB/35
or its equivalent.
17. ☐ Other: _____

18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: filed

Prior application information: Examiner: _____ Group Art Unit: _____

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

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24353

or ☐ Correspondence address below

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Bret E. Field

Registration No. (Attorney/Agent)

37,620

Signature

Date

August 1, 2003

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

APPLICATION INFORMATION

Application Type::

Title::

Utility

PROSTHETIC INTERVERTEBRAL
DISC AND METHODS FOR USING
THE SAME
DKIM-001

Attorney Docket Number::

Request for Non-Publication?::

Assignee for Publication::

Total Drawing Sheets::

11

Small Entity?::

Yes

License US Govt. Agency::

Contract or Grant Numbers::

Sequence Submission?::

Computer Readable Form (CRF)?::

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REPRESENTATIVE INFORMATION

Representative Customer Number:: 24353

CONTINUITY INFORMATION

This application is a::
> Application One::
Filing Date::

This application is a::
> Application Two::
Filing Date::

which is a::
>> Application Three::
Filing Date::

which is a::
>>> Application Four::
Filing Date::

PRIOR FOREIGN APPLICATIONS

Foreign Application One::
Filing Date::
Country::
Priority Claimed::